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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,316	07/13/2006	Lothar Gobel	KCX-1252-PCT-US (64355278)	7381
7590 Stephen E. Bondura Dority & Manning, P.A. P.O. Box 1449 Greenville, SC 29602			EXAMINER FLICK, JASON E	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 09/13/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,316	Applicant(s) GOBEL, LOTHAR	
	Examiner JASON FLICK	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Examiner acknowledges the reply filed on 06/30/2010 in which no claims were amended. Claims 10 and 11 have been cancelled. Currently, claims 1-9 and 12-25 are pending for examination in this application.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 13, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Williamson, IV (USPN 5,545,179).

4. [Claims 1-6, 13, 21, and 22] Williamson, IV (hereinafter Williamson) teaches a closing system for a natural or artificial anus, comprising: a first cylindrical outer sleeve (figure 5, item 25) defining a first lumen with a first diameter (figure 5, item 31) and a second cylindrical inner sleeve (figure 5, item 27) defining a second lumen with a second diameter (figure 5, item 44) and comprising an air channel (figure 6, item 38), said second sleeve having a portion nesting within the first lumen of said first sleeve (figures 5 and 6), an inflatable thin-walled polyurethane (column 5, lines 42-44) balloon (figure 5, item 26), preformed with two connection ports or ends (figure 6, items 34 and 35), having a generally toroidal structure, formed of a hose segment with a two-

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dimensional surface and defining a first and a second end, which hose segment is inverted into itself to define an inner wall and an outer wall and wherein the portion of the inner wall of the inflated balloon disposed internally of the wearer defining an internal area configured without any rigid guide shaft therein that otherwise might project into the wearer's intestine (figure 6), whereby its two ends extend generally coaxially with each other and said first end is connected to said first sleeve (figure 6) and forms a continuous pathway with said first lumen and said second end is connected to said second sleeve and forms a continuous pathway with said second lumen; characterized in that said connection ports or ends of said balloon are preformed to have a generally constant cross-sectional length (figures 5 and 6), wherein the two ends of the inverted hose have different lengths that correspond to different circumferential lengths of said end regions (figures 5 and 6); wherein the inverted hose is preformed such that its front end, which is distal relative to the mutually coaxial ends, assumes in an inflated state a gently curved contour with no edge regions (figures 5 and 6); and wherein said balloon is preformed such that it has in an inflated state a diameter that exceeds a diameter of a bowel segment (figures 10 and 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179).

8. [Claim 7] Williamson teaches the limitations of claim 6, upon which claim 7 depends. Williamson does not specifically disclose the length of each sleeve is smaller than one third the length of the balloon measured coaxially to the axis of symmetry of the inflated balloon. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the claimed dimensions, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. Claims 8, 9, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Kieturakis (USPN 5,667,479).

10. [Claim 8] Williamson teaches the limitations of claim 6, upon which claim 8 depends. Williamson does not specifically disclose the collapsed balloon is housed in a cavity. However, Kieturakis teaches a surgical resection instrument comprising a collapsible balloon (figure 3, item 40) housed in a cavity (figure 3, item 30), which is

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provided in a plug (figure 3, item 10) and is directed toward an interior of the bowel. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson with the balloon storage capability, as taught by Kieturakis, in order to provide sufficient protection for the balloon structure during insertion and removal of the system within a patient.

11. [Claim 9] Williamson and Kieturakis teach the limitations of claim 8, upon which claim 9 depends. In addition, Williamson teaches that the two connection ports of said balloon are each connected by their mouths to a plug (figures 5 and 6).

12. [Claim 12] Williamson teaches the limitations of claim 1, upon which claim 12 depends. Williamson does not specifically disclose that the balloon can be pulled through the outer sleeve. However, Kieturakis teaches the balloon can be pulled through the outer sleeve (figure 3; column 4, lines 18-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson with the balloon manipulation capability, as taught by Kieturakis, in order to provide sufficient protection for the balloon structure during insertion and removal of the system within a patient.

13. [Claim 23] Williamson teaches the limitations of claim 1, upon which claim 23 depends. Williamson does not specifically disclose a ring-shaped element for fixing the hose element to the central lumen. However, Kieturakis teaches a surgical resection instrument comprising a ring-shaped element (figure 3, item 68) which is fixed in a central lumen (figure 3, item 44) of the hose segment inverted into itself, the fixing being effected only along a narrow, circumferentially surrounding line so as not to deteriorate

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the freedom of movement of the balloon. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson with the use of a ring-shaped fixing element, as taught by Kieturakis, in order to provide a means of securing and preventing movement of the balloon.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Haber et al. (USPN 4,850,953).

15. [Claim 14] Williamson teaches the limitations of claim 13, upon which claim 14 depends. Williamson does not specifically disclose that the air channel comprises a stop valve. However, Haber teaches a closing system comprising an air channel which comprises a stop valve (figure 3, item 34). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson with the use of a stop valve, as taught by Haber, in order to provide increased control over the inflation and deflation of the balloon.

16. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Kieturakis (USPN 5,667,479), in further view of Haber et al. (USPN 4,850,953).

17. [Claims 16-18] Williamson and Kieturakis teach the limitations of claim 8, upon which claims 16-18 depend. Although Williamson teaches a sealing cap and Kieturakis teaches a plug, Williamson and Kieturakis do not specifically disclose a plug in adjacent contact to a sealing cap. However, Haber teaches a closing system comprising a plug (figure 1, item 6) connectable to a sealing cap (figure 1, item 2), connected adjacent contact to said plug and has a folded structure. It would have been obvious to one of

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ordinary skill in the art at the time of the invention to modify the structure taught by Williamson and Kieturakis with the use of a plug and sealing cap relationship, as taught by Haber, in order to provide sufficient protection for the balloon structure during insertion and removal of the system within a patient.

18. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Mulhauser et al. (PGPub 2003/0181879).

19. [Claim 15] Williamson teaches the limitations of claim 1, upon which claim 15 depends. Williamson is silent on the use of a carbon filter. However, Mulhauser teaches a sealing device comprising a carbon filter which can be disposed inside the inner sleeve (figure 4, item 30; paragraph [0068]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson with the use of a carbon filter, as taught by Mulhauser, in order to provide a means of purifying the air passing through the device.

20. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Kieturakis (USPN 5,667,479), in view of Haber et al. (USPN 4,850,953), in further view of Salama (USPN 6,527,755).

21. [Claims 19 and 20] Williamson, Kieturakis, and Haber teach the limitations of claim 16, upon which claims 19 and 20 depend. Williamson, Kieturakis, and Haber do not specifically disclose the use of a collection bag. However, Salama teaches a sealing device comprising a sealing cap (figure 3, item 38) and/or said plug which is connectable to a collection bag (figures 3 and 4, item 58), wherein the collection bag is connectable to said sealing cap (figure 3, item 38) and to the inner sleeve (figure 3, item

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40). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson, Kieturakis, and Haber, with use of the sealing cap and collection bag combination, as taught by Salama, in order to provide a means of controlling and/or collection material flowing into or out of the device.

22. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williamson, IV (USPN 5,545,179), in view of Kieturakis (USPN 5,667,479), in further view of Kim (USPN 5,569,216).

23. [Claim 24] Williamson and Kieturakis teach the limitations of claim 23, upon which claim 24 depends. Williamson and Kieturakis do not specifically disclose an externally controllable sealing element in the form of a separately inflatable balloon. However, Kim teaches a multipurpose sealing device comprising an externally controllable sealing element in the form of a separately inflatable balloon (figure 3, item 110), which is disposed in the central lumen of a hose element inverted into itself (figure 3, item 100). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the structure taught by Williamson and Kieturakis, with the use of an additional sealing element, as taught by Kim, in order to provide a means of controlling flow through the lumen of the hose segment.

24. [Claim 25] Williamson, Kieturakis, and Kim teach the limitations of claim 24, upon which claim 25 depends. In addition, Williamson discloses a tube can be inserted through the central lumen of the hose segment inverted into itself (figures 10 and 11).

Response to Arguments

25. Applicant's arguments filed 06/30/2010 have been fully considered but they are not persuasive. Applicant's representative asserts that the prior art of record does not disclose the invention as claimed.

26. Examiner has fully considered the applicant's arguments but they are not persuasive. It is the examiner's position that given a careful reading, the claims do not distinguish over the prior art of record.

27. Applicant's representative's asserts that Williamson does not teach a structure "for a natural or artificial anus." The examiner respectfully disagrees. It is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963). Where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function. In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). In addition, where there is a reason to believe that such functional limitation may be an inherent characteristic of the prior art reference, Applicant is required to prove that the subject matter shown in the prior art reference does not possess the

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characteristic relied upon. In re Spada, 911 F.2d 705, 15 USPQ2d 1655 (Fed. Cir. 1990); In re King, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 441 F.2d at 664, 169 USPQ at 566 (CCPA 1971).

28. Applicant's representative also asserts that structures taught by Williamson do not teach the limitations of claim 1, specifically regarding the connection of the first and second end of the balloon to the second sleeve. The examiner respectfully disagrees. Applicant's representative's argument rests on the interpretation of the phrase "connected to." Given the broadest reasonable interpretation, "connected to" does not require direct, physical contact, but only merely indicates a joined or linked relationship. For example, a telephone could be considered "connected to" a wall outlet via a telephone cord. The current claim language does not require a monolithic connection. Given this interpretation, it is quite clear that the structure taught by Williamson meets the claim limitation.

29. Therefore, the examiner asserts the prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./

Examiner, Art Unit 3763

09/09/2010

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763